

The new ground of rejection raised in the "Final" Office Action was a modification of the previous rejection under 35 U.S.C. 102(b), based on the Tune et al. patent (USP 5,630,710). In particular, the "Final" Office Action includes a rejection of claim 15 over Tune et al., where that claim was not rejected over Tune et al. in the first Office Action. In addition, in the "Final" Office Action, the Examiner refers to and applies different elements from the Tune et al. patent to the pending claims than were referred to in the first Office Action.

More specifically, in the first Office Action dated July 9, 2002, claims 1-3, 5-8, 10, 12-14 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by Tune et al. In the first Office Action, claim 15 was rejected under 35 U.S.C. 102(b) as being anticipated by Snell et al. (USP 5,759,199), but was not rejected over the Tune et al. patent. However, in the "Final" Office Action, the rejection over the Snell et al. patent is not re-asserted, but claim 15 is now included in the claims (i.e., claims 1-3, 5-8, 10 and 12-16) that are now rejected under 35 U.S.C. 102(b) as being anticipated by Tune et al. Thus, the "Final" Office Action includes a new ground of rejection of claim 15 over the Tune et al. patent. That new ground of rejection was not necessitated by an amendment to claim 15 (claim 15 has not been amended).

In addition, the Examiner has cited and applied different elements from the Tune et al. patent to address certain claim features in the "Final" Office Action than were cited in the first Office Action. More specifically, in the first Office Action, the Examiner stated that Tune et al. disclosed a communication device (CD) having many of the features recited in the rejected claims. The Examiner identified Tune et al.'s "CD processor" as reference number 576 and described the processor as "providing visual feedback to the patient" (first Office Action, page 3, lines 13 and 14). The cited element 576 is a multiplexer located in the infusion pump 10 (i.e., the patient side of the Tune et al. system).

Similarly, in the first Office Action (and the recent Final Office Action), further elements of Tune et al.'s infusion pump 10 were cited as corresponding to features of the communication device CD in the rejected claims. In particular, Tune et al.'s disclosure, at column 3, lines 29-47, was cited as disclosing features and the functions of the communication device (CD) display, including:

"a CD display controlled by at least one CD processor (576) for providing visual feedback to the patient, and wherein the feedback comprises a display of the quantity of a consumable estimated to be remaining in the system (512), ... wherein infusion parameters can be selected, and where the patient can program (28) their own options into the pump. (Column 3, lines 29-47)" (See, first Office Action, page 3, lines 13-18).

All of the features described in the above-cited portion of the Tune et al. patent (column 3, lines 29-47) are on the "patient" side of the system, i.e., the infusion pump 10 which connects to the patient user. In particular, the "user interface," the "user display" and other components are all described as being within the same housing as the "pumping mechanism", (e.g., see reference to "a housing" containing a "pumping mechanism" on lines 31-32 of column 3 and, then, to "the housing" containing the user display device and user interface on line 41 of column 3).

Thus, the first Office Action only referred to elements in the patient pump side of the system (the multiplexer 576 and the user interface and display device on the pump 10) as corresponding to the claimed "communication device" (CD). In contrast, in the January 2, 2003 "Final" Office Action, the programmer 952 has now been identified as corresponding to the claimed "communication device" (CD). The Examiner stated "Tune et al. discloses a medical infusion pump (Ref. # 10), which is the medical device, and a programmer (Ref. # 952) which is the communication device, not the control panel as implied by the applicant in the arguments ..." ("Final" Office Action, page 7, first paragraph).

The programmer 952 was not cited in the first Office Action as corresponding to the "communication device" in the claims. Instead, as noted above, the Examiner cited elements of the pump 10 (including multiplexer 576 and display features described in column 3, lines 29-41 of the Tune et al. patent) as corresponding to features of the "communication device" (CD). That change of the rejection in the "Final" Office Action to refer to Tune et al.'s programmer 952 as corresponding to the "communication device" (CD) forms a new ground of rejection. That new ground of rejection was not necessitated by any amendments to the claims.

Accordingly, it is respectfully submitted that the "Final" status of the Office Action dated January 2, 2003 should be withdrawn. Moreover, it is respectfully submitted that, by the present Amendment, the application is in condition for allowance. Therefore, entry and consideration of the present Amendment is requested.

Claims 1-3, 5-8, 10 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tune et al. (U.S. Patent No. 5,630,710). With respect to cancelled claims 1-3 and 5, this rejection is moot. With respect to amended claims 6 and 12 and dependent claims 7, 8, 10 and 13-16, this rejection is respectfully traversed.

Claims 6-8, 10 and 12-16 recite a medical system having features that are neither described nor suggested by the Tune et al. patent. For example, the medical system of claims 6-8 and 10 includes:

1. a communication device CD that "includes a CD display controlled by the at least one CD processor for providing visual feedback to the patient;" and
2. a communication device CD telemetry system that "sends messages to or receives messages from the MD telemetry system using RF transmissions"

Tune et al. neither describes nor suggests a medical system as claimed, including the above-noted features. In the "Final" Office Action, the Examiner cites the programmer 952 of the Tune et al. system as corresponding to the "communication device" CD ("Final" Office Action, page 7, first paragraph.) However, the programmer 952 is described by Tune et al. as a "remote programmer" for programming the pump 10 from a remote location relative to the pump and patient.

Because it is designed to be used remotely from the pump and patient, Tune et al.'s "remote programmer" does not include "at least one CD display controlled by the at least one CD processor for providing visual feedback to the patient." While it is contemplated that the remote programmer 952 may be positioned in IR communication with the pump 10 during a programming operation, the display and processor in the remote programmer 952 provide visual feedback to the programming technician, not to the patient. Instead, Tune et al. provide a patient-side display on the pump 10 for providing visual information to the patient (see, e.g., control panel 32 and "patient display 36" on the pump 10). There would be no reason or motivation for the display

device in the programmer 952 to provide a visual display to the patient, because the patient already has a visual display in the pump 10. However, the patient-side display in the pump 10 employs the pump processor and, thus, does not employ a separate communication device processor. This distinction was described in greater detail in the response to the first Office Action as a reason why components of the pump 10 would not meet the communication device CD features recited in the claims under rejection.

Accordingly, it is respectfully submitted that Tune et al. neither describe nor suggest a medical system in which a communication device CD "includes a CD display controlled by the at least one CD processor for providing visual feedback to the patient;" as recited in claims 6-8, 10.. Thus, the rejection of claims 6-8 and 10 is respectfully traversed.

In addition, the programmer 952 (cited by the Examiner as corresponding to the communication device CD in the claims) does not send messages to or receive messages from the MD telemetry system "using RF transmissions," as recited in amended claim 6 (and, thus, dependent claims 7, 8 and 10). Instead, Tune et al. describe an infrared (IR) link to the pump 10 (through the infrared window 70) or a combination of a telephone line and infrared link. The IR communication link requires a direct line of sight with the pump 10, for communication to occur. Specifically, Tune et al. state: "When the remote programmer (952) is physically remote, it cannot directly transmit IR signals to the pump (10). In that instance, the programmer (952) transmits programming information over commercial phone lines to the RCIU (950), which converts the information to infrared signals to the pump (10), and vice versa" (see col. 29, lines 21-26). Such a system would not work for implantable medical devices, and would have completely different CD electronic control circuitry than claimed in the present application. Accordingly, the claimed system, which uses RF transmissions, provides a significant advantage over the Tune et al. system, in that embodiments of the claimed system may be capable of use in an implant environment. (Note that claims 9 and 15 recite implantable features.) Thus, the rejection of claims 6-8 and 10 is further respectfully traversed.

Claims 12-16 recite a medical system also having features that are neither described nor suggested by the Tune et al. patent. For example, the system of claims 12-16 includes:

1. a CD display that "is controlled to depict a plurality of patient programmable options and wherein at least one of the patient programmable options may be enabled or disabled such that when disabled the at least one patient programmable option is no longer displayed as an option," and

2. a communication device CD telemetry system that "sends messages to or receives messages from the MD telemetry system using RF transmissions"

As discussed above, because it is designed to be used remotely from the pump and patient, Tune et al.'s "remote programmer" 952 does not include "at least one CD display controlled by the at least one CD processor for providing visual feedback to the patient." Similarly, Tune et al.'s "remote programmer" 952 does not include a CD display that is controlled to depict a plurality of patient programmable options. The remote programmer 952 is remote from the patient and, thus, would not display patient programmable options, as claimed.

Also as discussed above, the programmer 952 (cited by the Examiner as corresponding to the communication device CD in the claims) does not send messages to or receive messages from the MD telemetry system "using RF transmissions," as recited in claims 12-16. Instead, Tune et al. describe an infrared (IR) link to the pump 10 (through the infrared window 70) or a combination of a telephone line and infrared link. Tune et al.'s system would not work for implantable medical devices, and would have completely different CD electronic control circuitry than claimed in the present application. Accordingly, the claimed system, which uses RF transmissions, provides a significant advantage over the Tune et al. system, in that embodiments of the claimed system may be capable of use in an implant environment. (Note that claims 9 and 15 recite implantable features.) Thus, the rejection of claims 12-16 is further respectfully traversed.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al, in view of Er (U.S. Patent No. 6,185,461). Claim 11 is dependent on claim 6. The Er patent does not address the above-noted distinctions between claim 6 and the Tune et al. patent. Accordingly, the rejection of claim 11 is respectfully traversed, at least for the reasons noted above with respect to claim 6.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Causy et al. (U.S. Pub. 2002/0002326). In addition, claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al (U.S. Pub. 2001/0037083). As claims 1-5 have been cancelled without prejudice, these rejections are moot.

Claim 9 was not cited in a rejection in the "Final" Office Action. Accordingly, it is submitted that claim 9 is patentably distinguished from the prior art of record. Furthermore, distinctions described above with respect to independent claim 6 would apply to claim 9, as well. Also, as discussed above, claim 9 recites implantable features that would be inconsistent with Tune et al.'s IR communication link.

In view of the forgoing, it is respectfully submitted that the application is in condition for allowance. Re-examination and reconsideration of the application, as amended, are requested.

If the Examiner believes that the application is other than in condition for allowance, the Examiner is requested to contact the undersigned attorney at the Los Angeles telephone number (310) 975-7963, to discuss any steps that the Examiner believes are needed to place the application in condition for allowance.

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